OMI®
OHIO MEDICAL INSTRUMENT COMPANY, INC.

JUL 2 9 2002

K021604

II. 510(k) SUMMARY

Summary of Safety and Effectiveness:
MAYFIELD® Radiolucent Skull Pins 4-0-A-2020

Pursuant to Section 513(i) of the Federal Food, Drug and Cosmetic Act, as amended by the Safe Medical Devices Act [SMDA] of 1990.

Summary Preparation Date: April 19, 2002

1. **General Information:**

Classification Name: Holder, Head, Neurosurgical (Skull Clamp)
Common/Usual Name: Skull Pins
Proprietary Name: MAYFIELD® Radiolucent Skull Pins

Applicant's/Submitter's Name and Address & Registration Number:

Ohio Medical Instrument Company, Inc. (OMI)
4900 Charlemar Drive
Cincinnati, OH 45227

Registration Number:	1525725
Contact Name:	Charles E. Dinkler II
Contact Title:	New Product Development Engineer
Contact Phone Number:	(513) 561-2241 ext. 2002
Contact Fax Number:	(513) 332-2000

2. **Name of predicate device(s):**

MAYFIELD Disposable Skull Pin 4-0-A-1072 (K923789)

3. **Classification:**

§882.4460 Neurosurgical Head Holder (skull clamp).
(a) Identification: A neurosurgical head holder (skull clamp) is a device used to clamp the patient's skull to hold head and neck in a particular position during surgical procedures.
(b) Classification: Class II (performance standards).

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II. 510(k) SUMMARY - continued

4. Performance Standards:

No applicable performance standards have been established by FDA under section 514 of the Food, Drug and Cosmetic Act.

5. Intended Use and Device Description:

Intended Use:
MAYFIELD Radiolucent Skull Pins are used with a skull clamp that is placed on the patient's skull to hold their head and neck in a particular position during surgical procedures when rigid skeletal fixation is desired and Intra-Operative CT or MRI imaging is used.

Indications for Use:
The MAYFIELD Radiolucent Skull Pins are indicated for use in open and percutaneous craniotomies and spinal surgeries when rigid skeletal fixation is necessary and when Intra-Operative CT or MRI imaging of the patient is used.

Device Description:
The MAYFIELD Radiolucent Skull Pin 4-0-A-2020 [radiolucent pin] consists of the following components:
- a molded black-color ABS plastic base, and
- a machined sapphire-crystal pin point.

The radiolucent pins are packaged three (3) pins per pouch, two (2) pouches per carton and EO sterilized.

The radiolucent pins are single-use devices used to rigidly fix the patient's head and/or spine during surgery. The radiolucent pins are assembled from two components; a molded ABS plastic base [the same as used in the predicate device, MAYFIELD Disposable Skull Pins 4-0-A-1072][A1072 pins] and a pin point made of sapphire crystal that is machined to the same dimensions as the A1072 pin point. In preparation for surgery three (3) radiolucent pins are installed in a MAYFIELD Radiolucent Skull Clamp; two radiolucent pins in the Rocker Arm side and a single radiolucent pin on the opposite side. The radiolucent pins are EO sterilized, just as the A1072 pins mentioned above, and are ready for use right from the sterile pouch.

6. Summary of Substantial Equivalence:

The MAYFIELD Radiolucent Skull Pins 4-0-A-2020 are substantially equivalent to the following devices:

- The MAYFIELD Disposable Skull Pins 4-0-A-1072, K923789.

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II. 510(k) SUMMARY - continued

6. Summary of Substantial Equivalence: (continued)

Indications:

- The indications for the MAYFIELD Radiolucent Skull Pins 4-0-A-2020 are identical to the indications for the predicate device, MAYFIELD Disposable Skull Pins 4-0-A-1072, currently marketed by OMI, with the following exception: The radiolucent pins are indicated for use when Intra-Operative CT or MRI imaging is used.

Design:

- Both the radiolucent pins and the A1072 Pins are used in MAYFIELD Skull Clamps for surgical approaches that require rigid skeletal fixation.
- Both systems may be used to treat the same medical or surgical conditions of the brain and cervical spine.
- Both systems have essentially the same cautions and contraindications for use.
- Head fixation devices have been in common use for many years. The Skull Pin allows the user to fixate the skull in a clamping device for improved reliability of CT or MR scan data. Technological advances have increased the demand to perform intra-operative surgery scans, which requires minimal artifact and necessitates compatible hardware such as the radiolucent pins. It is anticipated that most neurosurgery physicians are extensively experienced in the use of a MAYFIELD Skull Clamp and MAYFIELD Disposable Skull Pins [the predicate device] and are expected to adapt readily to the use of the MAYFIELD Radiolucent Skull Pins.

Materials:

- Both the radiolucent pins and the predicate device utilize the same molded base made of the same ABS plastic material, the same sterilizable TYVEK/flexible film pouch and the same other packaging materials that meet the various BS, ISO and ASTM standards. The radiolucent pin point is made from sapphire crystal/ crystal alumina [aluminum oxide] while the A1072 pin point is made of 17-4PH stainless steel.

Performance:

- Results of comparisons of Penetration Testing with Axial Loading, Penetration Testing with Axial Loading and Shear Loading demonstrate that the radiolucent pins perform substantially the same as the predicate device. Multiple Penetration Tests with Axial Loading and Penetration Tests with Axial Loading and Shear Loading were run with the radiolucent pins and with the predicate device. The tests' results show the radiolucent pins performance is equal to that of the predicate device. There were no device failures during these tests.

- Results of comparisons of CT Images of a melon held by radiolucent pins and a melon held by stainless steel pins [predicate device] show significantly less artifact resulting with the radiolucent pins than with the stainless steel [predicate device] pins.

II. 510(k) SUMMARY - continued

7. Packaging:

The MAYFIELD Radiolucent Skull Pins [radiolucent pins] are supplied in the same packaging that is used by the predicate devices - industry standard medical grade packaging [sealed TYVEK/flexible film pouches] suitable for sterile surgical devices. Cartons and shippers are of suitable design and materials to ensure product sterility, identification and protection from damage during shipping and storage and are the same as or equivalent to that used by the predicate device.

8. Sterilization:

The radiolucent pins are supplied to the surgeon **STERILE**, as are the predicate devices. These devices are cleaned by OMI using a validated process to remove manufacturing residue, then they are assembled with the base, shipped to the contract assembler/packager where they are assembled/packaged in a controlled environment assembly/packaging area and sealed. The sealed pouches are then sterilized using a validated Ethylene Oxide sterilization cycle, based upon ANSI/AAMI/ISO 11135-1994, Medical Devices - Validation and Routine Control of Ethylene Oxide Sterilization and the corresponding European/British standard EN 550:1994. The Sterility Assurance Level (SAL) of the validated sterilization cycle is 10^{-6} (SAL 10^{-6}). The radiolucent pins are packaged and sterilized in exactly the same manner as are the predicate devices.

9. Conclusion:

The radiolucent pin points are machined and the plastic bases are molded, in exactly the same manner as are the predicate device [A1072 pins]. The radiolucent skull pins are then assembled, cleaned, assembled/packaged, and sterilized in exactly the same manner as are the predicate device [A1072 pins].

The Penetration Tests that were conducted comparing the radiolucent pins to the A1072 pins show them to be equivalent, and the CT Imaging artifact comparison show the radiolucent pins are superior to the predicate device [A1072 pins].

Based on the information provided above, Ohio Medical Instrument Company, Inc. considers the MAYFIELD Radiolucent Skull Pins 4-0-A-2020 to be substantially equivalent to the predicate device, MAYFIELD Disposable Skull Pins 4-0-A-1072.

II. 510(k) SUMMARY - continued

10. Comparison Table

FEATURE	MAYFIELD Radiolucent Skull Pins 4-0-A-2020	MAYFIELD Disposable Skull Pins 4-0-A-1072	SE?
Intended Uses:	• Used with the MAYFIELD Radiolucent Skull Clamp 4-0-A-2002 to clamp the patient's skull and hold the head and neck in position during surgical procedures in which Intra-Operative CT or MRI imaging is used.	• Used with the MAYFIELD 2000 Skull Clamp 4-0-A-2000 to clamp the patient's skull and hold the head and neck in position during surgical procedures.	YES
Indications for Use:	• Indicated for use in open and percutaneous craniotomies and spinal surgeries when rigid skeletal fixation is necessary and when Intra-Operative CT or MRI imaging is used.	• Indicated for use in open and percutaneous craniotomies and spinal surgeries when rigid skeletal fixation is necessary.	YES
Materials:	• The pin point is machined sapphire crystal [aluminum oxide] and the molded base is ABS plastic.	• The pin point is machined stainless steel and the molded base is ABS plastic.	YES
Manufacturing:	• The pin point is machined to the dimensions listed on the radiolucent pin point drawing which lists same dimensions as the stainless steel pin point drawing. • The pin base is the same as the pin base used for the predicate device and is molded to the dimensions listed on the pin base drawing.	• The pin point is machined to the dimensions listed on the stainless steel pin point drawing. • The pin base is molded to the dimensions listed on the pin base drawing.	YES
Preparation for Surgery:	• None, the pins are supplied sterile in a 3-pack pouch, ready for use.	• None, the pins are supplied sterile in a 3-pack pouch ready for use.	YES
Method of Use:	• Three (3) pins are installed in receptacles of a MAYFIELD Radiolucent Skull Clamp 4-0-A-2002 [K953124]	• Three (3) pins are installed in receptacles of a MAYFIELD 2000 Skull Clamp 4-0-A-2000 [K932807].	YES
Performance:	• Penetration Testing -Axial Load Repeated penetrations with no degradation of point. -Axial & Side Load Sustained side forces exceeding safety factor of 2	• Penetration - -Axial Load Repeated penetrations with no degradation of point. -Axial and Side Load Sustained side forces exceeding safety factor of 2.	YES
K-Number:	• To Be Assigned	• K923789	YES
Manufacturer:	• Ohio Medical Instrument Company, Inc.	• Ohio Medical Instrument Company, Inc.	YES

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 2 9 2002

Mr. Charles E. Dinkler II
Ohio Medical Instrument Company, Inc.
4900 Charlemar Drive
Cincinnati, Ohio 45227

Re: K021604
Trade/Device Name: Mayfield® Radiolucent Skull Pins Model 4-0-A-2020
Regulation Number: 882.4460
Regulation Name: Neurosurgical Head Holder (Skull Clamp)
Regulatory Class: II
Product Code: HBL
Dated: May 6, 2002
Received: May 16, 2002

Dear Mr. Dinkler:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K021604

Device Name: MAYFIELD® Radiolucent Skull Pins A-2020

Indications For Use:

The MAYFIELD® Radiolucent Skull Pins A-2020 are intended for use with a skull clamp that is placed on the patient's skull to hold their head and neck in a particular position during surgical procedures when rigid skeletal fixation is desired and Intra-Operative CT or MR imaging is used.

The MAYFIELD® Radiolucent Skull Pins A-2020 are Indicated for use in open and percutaneous craniotomies and spinal surgeries when rigid skeletal fixation is necessary and when Intra-Operative CT or MR imaging of the patient is used.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N Milhous

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K021604

Prescription Use X OR Over-The-Counter Use ___
(Per 21 CFR 801.109)

(Optional Format - 1 - 2 - 96)